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PCT

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference AGI-127 PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/24659	International filing date (day/month/year) 08 SEPTEMBER 2000	Priority date (day/month/year) 10 SEPTEMBER 1999
International Patent Classification (IPC) or national classification and IPC IPC: AG1K 31.19 and US CL: 514.557		
Applicant APPLIED GENETICS INCORPORATED DERMATICS		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

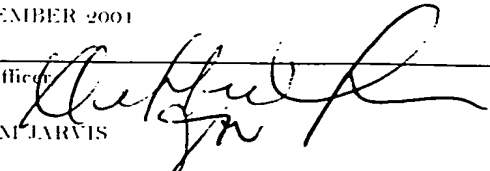
2. This REPORT consists of a total of 3 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and or drawings which have been amended and are the basis for this report and or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 06 APRIL 2001	Date of completion of this report 10 DECEMBER 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  WILLIAM JARVIS
Facsimile No. (703) 305-3230	Telephone No. (703) 308-1235

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/24659

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☒ the description:  
pages 1-25, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages 26-29, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the drawings:  
pages 1-8, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the sequence listing part of the description:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets ~~4~~ NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)) \*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/24659

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. statement**

Novelty (N)	Claims	<u>1-38</u>	YES
	Claims	<u>NONE</u>	NO
Inventive Step (IS)	Claims	<u>NONE</u>	YES
	Claims	<u>1-38</u>	NO
Industrial Applicability (IA)	Claims	<u>1-38</u>	YES
	Claims	<u>NONE</u>	NO

**2. citations and explanations (Rule 70.7)**

Claims 1-38 meet the criteria for novelty under PCT Article 33(2) since the prior art fails to anticipate the claims.

Claims 1-38 lack an inventive step under PCT Article 33(3) as being obvious over Seki et al, Sang et al, Kim et al, and/or Granger et al. Seki teaches that ursolic acid is effective at treating acne vulgaris. Sang and Kim teach that ursolic acid is effective at providing a photoprotective effect against photoaging of cultured dermal fibroblasts. Granger discloses skin care compositions containing retinoids and various polycyclic triterpene carboxylic acids including ursolic acid for the treatment of various skin conditions including photodamaged skin, aged skin, acne, atopic dermatitis, etc. See particularly columns 1-3. Some of applicant's claims differ in that they require treatment of ichthyosis or ichthyosiform dermatoses. However, to treat these conditions is obvious since the skilled artisan would reasonably expect that compounds known to be effective at treating atopic dermatitis would be effective at treating ichthyosis and ichthyosiform dermatoses as well. To employ a steroid in the composition is obvious since antiinflammatory steroids such as hydrocortisone are conventionally employed in dermatological compositions. To encapsulate the compounds in liposomes is obvious since many active ingredients of dermatological compositions are employed in liposomes in order to improve the stability and bioavailability of the composition.

Claims 1-38 meet the criteria for industrial applicability under PCT Article 33(4) since the claims clearly have utility to one skilled in the dermatological arts.

----- NEW CITATIONS -----

NONE

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
 US Department of Commerce  
 United States Patent and Trademark  
 Office, PCT  
 2011 South Clark Place Room  
 CP2/5C24  
 Arlington, VA 22202  
 ETATS-UNIS D'AMERIQUE  
 in its capacity as elected Office

Date of mailing (day/month/year) 02 August 2001 (02.08.01)	
International application No. PCT/US00/24659	Applicant's or agent's file reference AGI.127 PCT
International filing date (day/month/year) 08 September 2000 (08.09.00)	Priority date (day/month/year) 10 September 1999 (10.09.99)
Applicant BROWN, David, A. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
06 April 2001 (06.04.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Olivia TEFY Telephone No.: (41-22) 338.83.38
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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US00/24659

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61K 31/19

US CL :514/557

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/557

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,723,139 A (GRANGER et al) 03 March 1998, see particularly columns 1, 2, and 10-12.	1-38
Y	Database DRUGU on STN, Derwent Information Ltd., No. 1996-25548, SANG, T. K. 'The effect of ursolic acid and all-trans-retinoic acid on ultraviolet A radiation induced elastin mRNA expression in cultured human dermal fibroblast,' abstract, J. Invest. Dermatol., 106(4), 836, 1996.	1-38

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

16 OCTOBER 2000

Date of mailing of the international search report

14 NOV 2000

Name and mailing address of the ISA/US  
Patent Office (to be filled in by the ISA/US)  
Box PCTAuthorized officer  
Telephone No. (703) 308-1235

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US00/24659

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Database <b>DRUGU</b> on STN, Derwent Information Ltd., <b>KIM, S. T.</b> et al. Accession No. <b>23729</b> 'The effect of all trans-retinoic acid, ursolic acid, ginseng, and aloe extract on ultraviolet A radiation induced collagenase mRNA expression in culture human dermal fibroblast,' abstract, J. Invest. Dermatol. 104(4), 621, 1995.	1-38
Y	Database <b>DRUGU</b> on STN, Derwent Information Ltd., <b>SEKI, T.</b> et al. Accession <b>28819</b> . 'Effect of Some Alkaloids and Flavonoids and Triterpenoids, Contents of Japanese-Chinese Traditional Herbal Medicines, on the Lipogenesis of Sebaceous Glands,' abstract, Skin Pharmacol. 6(1), 56-60, 1993.	1-38

## INTERNATIONAL<sup>1</sup> SEARCH REPORT

International application No.  
PCT/US00/24659

### B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

BRS (WEST), STN (CA), BIOSIS, MEDLINE, DRUGU, EMBASE)

search terms: skin, epidermis, lipids, aging, atrophy, inflammation, ceramides, phospholipids, photoaging, acne, ichthyosis, dermatosis, dermatitis